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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,711	05/18/2006	Ben Croker	19413	3843

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EXAMINER	
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1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,711	CROKER ET AL.	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-12,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-22-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 13-15 drawn to a method for modulating G-CSF-induced cellular responses via a SOCS molecule comprising administering a compound that elevates SOCS-3 level in the reply filed on June 13, 2008 is acknowledged. The traversal is on the ground(s) that "The examiner should not rely on an evaluation regarding novelty and/or inventive step of the present invention over certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1". This is not found persuasive because the assessment of the lack (or presence) of unity of invention or special technical features over the prior art requires evaluation of prior art teachings in relation to the instantly claimed inventive concept. That is, the Office has an obligation to determine whether the claimed invention defines a contribution over the prior art under 35 U.S.C. 121 and 372 in order to issue an election/restriction requirement. Since it is found that the claimed invention lacks special technical features that defines a "contribution" over the prior art teachings of Hortner et al., it is concluded that the inventions listed as Groups I-V (see the Office action dated May 21, 2008) do not relate to a "single" inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/AU/00749 filed on June 4, 2004 and a foreign priority document

2003902788 filed on June 4, 2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a).

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, the claims are drawn to methods for modulating G-CSF-induced cellular responses in a mammal comprising administering an effective amount of an isolated "compound" that elevates SOCS-3 level. The instant specification teaches that the "compounds of the present invention may be chemical molecules, peptides, polypeptides or proteins, or genetic molecules including nucleic acid molecules (such as sense and antisense molecules), RNAi or siRNA or complexes containing the same". See page 6, lines 1-3. With regard to the claimed "G-CSF-induced cellular responses", the specification teaches that they include "neutrophil recovery after chemotherapy or radiotherapy, mobilizing stem and progenitor cells, treating infection and treating inflammatory conditions". See page 1, lines 15-18. Hence, the claims encompass a wide variety of species within the claimed genus of compounds that elevate SOCS-3 level in a mammal wherein the genus of compounds perform any of the various functions within the claimed genus of modulating G-CSF-induced cellular responses such as neutrophil recovery, mobilizing stem and progenitor cells, and treating inflammatory conditions.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one

must describe a sufficient variety of species to reflect the variation within the genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

In the instant case, the specification does not describe even a single species within the claimed compound, which elevates SOCS-3 level in a mammal when applied to the mammal, thereby modulating G-CSF-induced cellular responses in the mammal, wherein the mammal is a human. As such, the specification fails to show an actual reduction to practice of the claimed invention for its intended purpose even for a single species embraced by the clamed genus of compounds. See MPEP 2163, which teaches the following: "A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) :"There cannot be a reduction to practice of the invention without a physical embodiment which includes all limitations of the claim."; *Estee Lauder Inc. v. L 'Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997): "A reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose." (emphasis added).

Furthermore, the specification does not provide any description of sufficient, relevant, identifying characteristics of the claimed invention (for example, the claimed compound that elevates SOCS-3 level and modulates G-CSF-induced cellular responses *in vivo* as claimed), and therefore, a person skilled in the art would not recognize that the inventors had possession of the claimed invention. Note that the claimed compound is a chemical invention. An adequate written

description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004), wherein the court expressed that an adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. (emphasis added). In fact, the patent at issue in the *Univ. of Rochester v. G.D. Searle & Co.* case is highly analogous to the claims at issue in the instant case. Note that the patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described." (emphasis added).

In light of the above, applicant's description of how to screen for drugs (see pages 15-17) or how to make the claimed compound such as polypeptides and polynucleotides (see pages 17-36) or how to administer the claimed compound into a mammal (see pages 37-42) or how to make and examine SOCS-3-deficient mice (see pages 43-53) is not a sufficient written description for the instantly claimed methods, which require a compound that elevates SOCS-3 level, which in turn must result in the claimed genus of modulating G-CSF-induced cellular

responses in a mammal including a human. Accordingly, one of ordinary skill in the art would not recognize that the inventors were in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hilton et al. (US 6,323,317 B1).

The claims are drawn to a method for modulating G-CSF-induced cellular responses in a mammal comprising administering a compound that elevates SOCS-3 levels, wherein the mammal is a human.

Hilton et al. teach a method of modulating G-CSF-mediated signal transduction in a human by administering a compound that increases levels and activity of a SOCS protein to the human, wherein the SOCS protein includes SOCS1, SOCS2, and SOCS3. See columns 19, lines 31-44; column 29, lines 13-28. Accordingly, all claim limitations are taught by Hilton et al.

Claims 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Filer et al. (US 2002/0142466 A1) as evidenced by Hortner et al. (*The Journal of Immunology,* 2002, 169:1219-1227, applicant's citation).

The claims are described above.

Filer et al. teach a method of inducing SOCS-3 expression by CNTF treatment or by administering a nucleotide construct encoding a SOCS-3 polypeptide in mammals including humans. See paragraphs 0008, 0052, 0114; claims 1, 8-10. Filer et al. do not explicitly teach that inducing SOCS-3 expression via CNTF treatment results in modulation of G-CSF-mediated signal transduction.

Hortner et al. teach that SOCS-3 is recruited to the activated G-CSF and modulates G-CSF-mediated signal transduction.

Hence, given the inherent biological property and characteristics of SOCS-3 to modulate G-CSF-mediated signal transduction, a person performing the method of Filer et al. would inherently and necessarily modulate G-CSF-induced cellular responses in humans, absent evidence to the contrary. Accordingly, the claimed invention is anticipated by Filer et al. as evidenced by the teachings of Hortner et al.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamanaka et al. (*Circulation Research,* 2001, 88:727-732) as evidenced by Hortner et al. (*The Journal of Immunology,* 2002, 169:1219-1227, applicant's citation).

The claims are described above.

Hamanaka et al. teach that SOCS-3 expression level is induced by treating rats with cardiotrophin-1 (CT-1) and suggest that CT-1-induced cytokine resistance can be applied for treating patients having cytokine-related diseases such as sepsis, myocarditis, and cardiomyopathy. See pages 728-731. Hamanaka et al. do not explicitly teach that inducing SOCS-3 expression via CT-1 treatment results in modulation of G-CSF-mediated signal transduction.

Hortner et al. teach that SCOS-3 is recruited to the activated G-CSF and modulates G-CSF-mediated signal transduction.

Hence, given the inherent biological property and characteristics of SOCS-3 to modulate G-CSF-mediated signal transduction, a person performing the method of Hamanaka et al. would inherently and necessarily modulate G-CSF-induced cellular responses in humans via CT-1 treatment, absent evidence to the contrary. Accordingly, the claimed invention is anticipated by Hamanaka et al. as evidenced by the teachings of Hortner et al.

Claims 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Peiser et al. (*Life Sciences,* 2000, 67:2971-2981) as evidenced by Hortner et al. (*The Journal of Immunology,* 2002, 169:1219-1227, applicant's citation).

The claims are described above.

Peiser et al. teach a method of inducing up-regulation of SOCS-3 mRNA levels by injecting leptin into rats. They teach that leptin stimulates the JAK/STAT cytokine signal transduction pathway and that SOCS-3 blocks leptin-induced JAK/STAT signal transduction.

See pages 2973, 2979-2980. Peiser et al. do not teach that inducing SOCS-3 expression via leptin treatment results in modulation of G-CSF-mediated signal transduction.

Hortner et al. teach that SCOS-3 is recruited to the activated G-CSF and modulates G-CSF-mediated signal transduction. Further, they teach that G-CSF specifically activates JAK/STAT signal transduction while SOCS-3 inhibits JAK/STAT signaling. See pages 1219-1224.

Hence, given the inherent molecular interactions between SOCS-3 and G-CSF and their functional implications in JAK/STAT signal transduction, a person performing the method of Peiser et al. would inherently and necessarily modulate G-CSF-induced cellular responses in rats via leptin treatment, absent evidence to the contrary. Accordingly, the claimed invention is anticipated by Peiser et al. as evidenced by the teachings of Hortner et al.

Claims 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (*The Journal of Clinical Investigation,* 2001, 107:1285-1292) as evidenced by Hortner et al. (*The Journal of Immunology,* 2002, 169:1219-1227, applicant's citation).

The claims are described above.

Campbell et al. teach a method of elevating SOCS-3 mRNA level by injecting TNF into wild-type mice. See Figure 5 and page 1289, 1291-1292. Campbell et al. do not explicitly teach that inducing SOCS-3 expression via TNF treatment results in modulation of G-CSF-mediated signal transduction.

Hortner et al. teach that SCOS-3 is recruited to the activated G-CSF and modulates G-CSF-mediated signal transduction.

Hence, given the inherent biological property and characteristics of SOCS-3 to modulate G-CSF-mediated signal transduction, a person performing the method of Campbell et al. would inherently and necessarily modulate G-CSF-induced cellular responses in wild-type mice, absent evidence to the contrary. Accordingly, the claimed invention is anticipated by Campbell et al. as evidenced by the teachings of Hortner et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19-20 of copending Application No. 11/977,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the reference claims embraces the method of the instant claims. The reference claims are drawn to a method of modulating signal transduction mediated by G-CSF in a cell containing a SOCS gene by administering a modulator of the SOCS gene, while the instant claims are drawn to a method of modulating G-CSF-induced cellular responses in a mammal by administering a modulator of SOCS-3. The specification of 11/977,132 discloses that the claimed "SOCS gene" encompasses any or all members of the SOCS family including SOCS1, SOCS2, and SOCS3. See page 6, lines 5-7. Further, the specification of 11/977,132 teaches that the claimed method of claims 17 and 19-20 embraces a method of modulating activity of SOCS in a human by administering a modulator that increases SOCS activity. See page 60, lines 8-11. Hence, the reference claims fully embrace the instantly claimed invention and therefore, a person of ordinary skill in the art would conclude that the invention defined in claims 13-15 at issue in the instant case would have been an obvious variation of the invention defined in claims 17 and 19-20 in the reference case, Application No. 11/977,132.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-47 of copending Application No. 11/598,212. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the reference claims overlaps with that of the instant claims. The reference claims are drawn to a method of increasing SOCS3 protein in a cell and a method of treating SOCS3-related condition in a subject, wherein each of the methods comprises administering a SOCS3 protein, while the instant claims are drawn to a method of modulating G-CSF-induced cellular responses in a mammal by administering a modulator that increases SOCS3 level in the mammal. The specification of 11/598,212 discloses that SOCS3 is essential in controlling G-CSF-induced cellular responses. See page 2, lines 8-9. Hence, although the reference claims do not explicitly recite modulating G-CSF-induced cellular responses, the method of treating SOCS3-related conditions in a subject or of increasing SOCS3 in a cell of the reference claims overlaps in scope with the method of modulating G-CSF-induced cellular responses as claimed in the instant claims at issue. Accordingly, a person of ordinary skill in the art would conclude that the invention defined in claims 13-15 at issue in the instant case would have been an obvious variation of the invention defined in claims 46-47 in the reference case, Application No. 11/598,212, and therefore, the conflicting claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
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Art Unit 1635

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Primary Examiner, Art Unit 1635